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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/697,028 10/25/00 STANTON V 11926-112001

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HM22/0717

EXAMINER

CHUNDURU, S

ART UNIT

PAPER NUMBER

1656

DATE MAILED:

07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/697,028

Applicant(s)

STANTON, VINCENT P.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-9 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Method claims require a last step or phrase in the last step that states the accomplishment of the goals for the method which were stated in the method's preamble. Claim 1 lack such a last step (how biasing the amplification is achieved) and is confusing because the additional method step is not sufficiently set forth. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashion. See Ex parte Erlich, 3 USPQ2d1011, p.1011 (Bd. Pat. App. Int. 1986). It is suggested that an amended claim more clearly describing the intended steps be submitted.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolla et al. (Clin Chem, 41 (11): 1599-1604, 1995) and in view of Caetano-Anolles et al. (Biotechniques, 20: 1044-1056, 1996).

Bolla et al. teach a method for genotyping of apo E using PCR- RFLP wherein Bolla et al. disclose that the method comprises (i) contacting a template DNA segment with two primers specific for two codons (E2/E3 alleles) (see page 1600, paragraphs 5-8); (ii) amplification of target DNA by PCR (see page 1601, paragraph 1); (iii) analyzing the amplified segment for the determination of allele (polymorphism) using restriction digestion of the amplified PCR products (see page 1601, paragraph 2). Further, Bolla et al. disclose that the presence of plurality of different size fragments in electrophoretic gel is indicative of different alleles (which differ in variation in a nucleotide present in polymorphic site). However, Bolla did not teach the use of primer containing non complementary region at 5'-end and formation of hairpin loop when hybridized to the target for priming.

Caetano-Anolles et al. teach a PCR method for DNA amplification fingerprints wherein Caetano-Anolles et al. disclose the use of hairpin PCR primer with 5'-end containing mini-hairpin (anchored simple sequence repeats or polymorphic region) and are used to detect polymorphic DNA with high efficiency (see page 1054, paragraphs 1-7). Further, Caetano-Anolles et al. disclose that the arbitrary selection of primers can be biased to include recognition of particular sequence motifs within genome and these primers were anchored at their 5' termini with degenerate bases (see page 1055, paragraph 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of detecting genotypes of apo E gene using PCR – RFLP as taught by Bolla et al. with the method of Caetano-Anolles et al. which is applicable to achieve rapid identification of alleles because Bolla et al. states that 'electrophoretic approach based on sizing is convenient for direct determination of haplotypes and as long as PCR becomes

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more routine, the direct characterization by PCR of haplotypes contingent on variations spaced hundreds or thousands of bases apart will become feasible'. One form of the feasibility, expressly motivated by Caetano-Anolles et al. is the use of hairpin PCR primers "to provide extensive screening of nucleic acids with only a limited number of primer sequences'. An ordinary practitioner would have been motivated to combine the method of Bolla et al. with the hairpin PCR primers of Caetano-Anolles et al. in order to achieve the expected advantage of detecting haplotypes of a gene.

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
July 13, 2001


JEFFREY FREDMAN
PRIMARY EXAMINER